## REMARKS

The Office Action dated January 3, 2006 and cited references have been considered. Claims 1-8 are presently pending. Reconsideration and allowance are respectfully requested.

On page 2 of the Office Action, the Examiner asserts that the presently pending claims are entitled only to the filing date of the present application, December 15, 2003. The Examiner bases this conclusion on the following remarks:

> In the documents identified above, there is no discussion of two bone screws being inserted through the same inserted cannula (as opposed to separate, spaced apart cannulae, for example) and no hint of any spinal rod or plate being inserted through said cannula; in fact, spinal rods and plates are not even mentioned.

Office Action at 2.

The Applicants respectfully disagree with the Examiner's conclusion. As discussed in detail below, the priority applications, including U.S. Patent No. 5,792,044, filed March 22, 1996, and U.S. Patent No. 5,902,231, filed October 24, 1996, fully satisfy the written description requirement with respect to pending claims 1-8 and new claim 9. Applicants are submitting herewith a Declaration of Dr. Kevin T. Foley (hereinafter "Foley Declaration") and a Proposed Rule and Comment of the U.S. Food and Drug Administration (FDA) for Classification, Reclassification and Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51946-51962 (October 4, 1995) (hereinafter "FDA Publication"). These documents provide the background as to the proper interpretation of Applicants' specification.

In the following sections of this Amendment, Applicants explain why the specification properly supports the claims and why the Examiner's position is incorrect. Key to an understanding of this argument is an understanding that the "invention" resides in the recognition by applicants that it was possible to conduct spinal surgery using a single cannula which could accommodate all instruments and elements needed for that surgery in a minimally invasive way; regardless of whether those elements are screws, hooks, plates, rods or other devices. Indeed, surgical procedures involving insertion of bone screws on adjacent vertebrae for and attachment of such bone screws with a rod or plate are part of the prior art and represent just one obvious species of the procedures that are possible using applicants' method.

(2)

**A. Legal Standard**

The test for sufficiency of support in a parent application is "whether the disclosure of the application being relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Vas-Cath Incorporated v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention. *Id.* at 1563-64, 19 USPQ2d at 1117. *In haec verba* support is not required. *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 1378, 56 USPQ2d 1445, 1455 (Fed. Cir. 2000). "If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

The question of whether a patent specification adequately describes the subject matter claimed is a question of fact. *In re Alton*, 76 F.3d at 1171, 37 USPQ2d at 1580. Precisely because it is a question of fact, an applicant can overcome a rejection by filing the Declaration of a person skilled in the art demonstrating that the specification reasonably conveys possession of the invention to such person skilled in the art. *See In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

**B. Arguments**

As discussed in detail below, the U.S. Patent and Trademark Office (USPTO) is believed to be in error in rejecting the claims under the written description requirement because:

**(i) The claims of the application as filed find written description support in the specification:**

1. The specification discloses performing the entire surgical procedure through a single cannula;

2. The specification discloses insertion of multiple vertebral fixation elements through the single cannula;

3. A pedicle screw is always used in combination with other fixation elements; and

4. The specification discloses repositioning the cannula to move the working space as necessary during the surgical procedure.

**(ii) Newly added claim 9 finds literal support in the originally filed application:**

Furthermore, even to the extent that the Patent Office continues to insist that the rejected claims lack adequate written description, applicants make reference to newly added claim 9 which find literal support in the original application and which clearly conveys the central inventive concept of conducting the entirety of a spinal surgery through a single tube in a minimally invasive way employing fixation elements including, *inter alia*, bone screws.

### 1. The Specification Discloses Performing the Entire Surgical Procedure Through a Single Cannula

In numerous instances, the '044 Patent states that the entire surgical procedure can be performed through a single cannula:

> In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula. '044 Patent at col. 4, lines 12-15.
>
> The techniques of the present invention also encompass passing multiple tools and instruments through the single working channel cannula and manipulating the instruments and tools within the working space. '044 Patent at col. 4, lines 19-22.
>
> Another advantage is realized in the use of a single portal within the patient to perform a wide range of simultaneous procedures. '044 Patent at col. 5, lines 34-36.
>
> Therefore, according to this invention, an entire percutaneous surgical procedure can be performed through the working channel 25 of the device 10 under direct visualization using the viewing element 50 disposed within the optics bore 60. '044 Patent at col. 7, lines 61-65.
>
> The present invention allows the use of but a single entry into the patient which greatly reduces the risk associated with open surgery or multiple invasions through the patient's skin. '044 Patent at col. 16, lines 25-29.
>
> Devices and methods for performing percutaneous spinal surgery under direct visualization and through a single cannula are shown. Abstract.

These repeated references to performing the entire surgical procedure through a single cannula clearly demonstrate that the Applicants were in possession of this concept as of March

22, 1996, the filing date of the '044 Patent. Applicants also point out that the specification clearly teaches that the size of the working channel cannula is selected such that it is appropriate to the procedure being performed. *See* '044 Patent at col. 12, lines 35-39 ("The present invention is not limited to particular sizes for the working channel and effective diameter, since the dimensions of the components will depend upon the anatomy of the surgical site and the type of procedure being performed."); '044 Patent at col. 10, lines 57-59 ("Larger working channel cannulas are contemplated depending upon the anatomical region and surgical procedure."). Therefore, the '044 Patent clearly discloses performing the entire surgical procedure through a single cannula of appropriate size for the procedure.

**2. The Specification Discloses Insertion of Multiple Vertebral Fixation Elements Through the Single Cannula**

The specification of the '044 Patent also clearly discloses the insertion of multiple vertebral fixation elements through the single working channel cannula:

> The insertion of vertebral fixation elements can also be accomplished through the device 10. In this type of procedure, an incision can be made in the skin posterior to the location of the vertebra at which the fixation element is to be implanted. Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented. With the optics extending through the working channel, an insertion tool holding the vertebral fixation element can be projected through the cannula 20 and manipulated at the vertebra.

'044 Patent at col. 15, lines 3-11.

As the first sentence of the paragraph quoted above indicates, it is the insertion of plural "vertebral fixation element**s**" which is accomplished through the device. At the time that the '044 Patent was filed (March 22, 1996), the term "vertebral fixation elements" would have been interpreted by one skilled in the art to mean elements or components of vertebral fixation systems, including at least bone screws, fixation plates and rods. Vertebral fixation elements, including bone screws, fixation plates and rods, were well known in the art at that time. Foley Dec. ¶ 17.

The patent cited by the Examiner (U.S. Patent No. 5,357,983), for example, discloses fixation instrumentation as including bone screws and fixation plates, among other elements. *See* U.S. Patent No. 5,357,983 at col. 2, lines 16-20 ("In general, this fixation hardware can include self-tapping cannulated bone screws, fixation plates and linking members for laterally

fixing plates on opposite sides of the spinous process."). Numerous other patents issued prior to the filing of the '044 Patent disclose vertebral fixation systems including bone screws, plates and rods. *See, e.g.*, U.S. Patent No. 5,196,015 at col. 1, lines 21-27 ("Instrument systems that accomplish spinal fixation are known in the form of pedicle screws which are adapted to be inserted in selected vertebrae, and stiff rods or plates that connect adjacent pedicle screw heads to one another after the screws are inserted, thus resulting in the fixing or bracing of all vertebrae spanned by the rod or plate."); U.S. Patent No. 5,382,248 at col. 1, lines 27-30 ("Internal fixation refers to methods of stabilization which are wholly internal to the patient and which include commonly known appliances such as bone plates or rods, hooks, and screws."); U.S. Patent No. 4,790,297 at col. 2, line 64 - col. 3, line 1 ("The preferred embodiment of the spinal fixation system 11 of the present invention is used for segmental fixation of the vertebrae V of a spinal column and comprises, in general, a substantially rigid spinal plate means or plate 13 and at least a pair of pedicule [sic: pedicle] screw means or screws 15."); U.S. Patent No. 5,395,371 at col. 1, lines 11-13 ("The invention concerns a fixation plate and bone screw system for attachment to vertebral bodies to hold the vertebrae in alignment.").

Other references demonstrate that bone screws, plates, and rods were well known elements of vertebral fixation systems at the time the '044 Patent was filed. For example, the FDA Publication submitted herewith describes bone screws, plates and rods as known elements of vertebral fixation systems. *See, e.g.*, FDA Publication at 51955 ("Pedicle screw spinal systems provide stabilization of vertebrae with longitudinal plates or rods attached to the vertebral bodies via screws through the pedicles."); *see also* FDA Publication at 51962 (defining a pedicle screw spinal system as a multiple component device comprising anchors (*e.g.*, bolts, hooks and screws); interconnection mechanisms incorporating nuts, screws, sleeves or bolts; longitudinal members (*e.g.*, plates, rods, and plate/rod combinations); and transverse connectors).

The aforementioned references show that (a) vertebral fixation systems were well known in the art at the time the '044 Patent was filed, (b) bone screws, plates and rods were well known elements of vertebral fixation systems at the time the '044 Patent was filed, and (c) one skilled in the art would interpret the term "vertebral fixation elements" to include at least screws, plates and rods as of the filing date of the '044 Patent.

Therefore, one skilled in the art would readily understand that the specification of the '044 Patent teaches inserting vertebral fixation elements, including at least bone screws, plates and rods, through the single working channel cannula. Applicants also note that the procedure of securing a first pedicle screw to a first vertebra, securing a second pedicle screw to a second vertebra, and securing a plate to the first and second pedicle screws was well known in the art. *See, e.g.*, U.S. Patent No. 5,395,371 at col. 6, lines 28-46 ("Once a pedicle screw means 40 has been threaded into each of the tapped openings in the vertebrae V, the fixation plate 13 can be placed against the arcuate surfaces 47 of each of the pedicle screw means 40. . . ."); U.S. Patent No. 5,196,015 at col. 1, lines 21-27 ("Instrument systems that accomplish spinal fixation are known in the form of pedicle screws which are adapted to be inserted in selected vertebrae, and stiff rods or plates that connect adjacent pedicle screw heads to one another after the screws are inserted, thus resulting in the fixing or bracing of all vertebrae spanned by the rod or plate.").

### 3. A Pedicle Screw Is Always Used in Combination with Other Fixation Elements

The specification of the '044 Patent describes a particular type of vertebral fixation element that is always used in combination with other vertebral fixation elements. In particular, the pedicle screw described in Applicants' specification is a fixation element that is always used in combination with a second anchoring-type fixation element (*e.g.*, a second pedicle screw or a hook) secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second fixation elements. Foley Dec. ¶ 18.

The proposed rule in the FDA Publication contains the following definition of a pedicle screw spinal system:

> A pedicle screw spinal system is a multiple component device, made of alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, unalloyed titanium, and Ti-6Al-4V that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of anchors (e.g., bolts, hooks, and screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and plate/rod combinations); and transverse connectors. The device is intended to provide immobilization and stabilization of spinal segments in the treatment of significant medical instability or deformity requiring fusion with instrumentation including significant medical instability secondary to spondylolisthesis, vertebral fractures, and dislocations, scoliosis, kyphosis, spinal tumors, and pseudarthrosis resulting from unsuccessful fusion attempts.

60 Fed. Reg. 51962 (October 4, 1995). This definition demonstrates that a pedicle screw is used in combination with other vertebral fixation elements, including a second anchoring-type fixation element (*e.g.*, a second pedicle screw or a hook) and another fixation element such as a plate or rod. In addition, the extensive comments in the FDA Publication, at pages 51946-51962, describe the use of pedicle screws only in combination with other vertebral fixation elements, such as plates and rods. One skilled in the art would therefore have understood that a pedicle screw would not be used alone, but rather would be used in combination with other vertebral fixation elements, *e.g.*, another pedicle screw or a hook secured to a second vertebra, and a third fixation element such as a plate or rod. Applicants also point out that the '044 Patent describes a procedure for fusing adjacent vertebrae together, *see* '044 Patent at col. 15, line 35 - col. 16, line 9, and at the time the '044 Patent was filed, it was quite common to facilitate the fusion of vertebrae by also installing a vertebral fixation system, such as two screws and a plate or rod, to fix the position of one vertebra with respect to the another vertebra, thus increasing the success rate of the fusion procedure.

**4. The Specification Discloses Repositioning the Cannula to Move the Working Space as Necessary During the Surgical Procedure**

The specification of the '044 Patent also discloses that the single cannula can be moved to different angles from a single incision site to perform the surgery:

> Another advantage provided by the single working channel cannula 20 of the present invention, is that the cannula can be readily positioned over an appropriate target tissue or bone, to thereby move the working space as necessary for the surgical procedure. In other words, since the working channel cannula 20 is freely situated within the patient's skin and tissue, it can be manipulated so that the working space beneath the cannula 20 is more appropriately centered over the target region of the spine. Repositioning of the cannula 20 can be performed under fluoroscopic guidance. Alternatively, the cannula may be fitted with position sensing devices, such as LEDs, to be guided stereotactically. As the cannula is being repositioned, the surgeon can also directly visualize the spine through the viewing element 50.

'044 Patent at col. 12, lines 3-16. This repositioning technique allows the surgeon to access various sites on different vertebrae with a single cannula during a surgical procedure. Foley Dec. ¶ 19. The description of this feature in the '044 Patent demonstrates that Applicants were in possession of this feature as of March 22, 1996, the filing date of the '044 Patent.

**5. Newly added claim 9 is literally supported by the originally filed application**

To further define the protection to which Applicants are entitled, applicants present new claim 9. In the first place, new claim 9 finds support in the disclosure of the '044 Patent for the reasons discussed above with respect to original claims 1-8. In the second place, it will be appreciated that above and beyond the arguments already set forth for claims 1-8, claim 9 finds near literal support in the original application. For example, the '044 Patent discloses inserting a cannula into a patient (col. 15, lines 7-9), moving a plurality of fixation elements through the cannula (col. 15, lines 3-4; col. 4, lines 12-15), installing the plurality of fixation elements at the surgical site to fix a first vertebra with respect to a second vertebra (col. 15, lines 3-34), and the fixation elements include bone screws (col. 15, lines 12-15). New claim 9 is patentable over the cited prior art references because it recites a combination of features that is not disclosed or suggested by the cited prior art references.

**C. Conclusion**

Based on the aforementioned teachings in the '044 Patent, it would have been readily apparent to one skilled in that art that the specification discloses inserting pedicle screws through a single cannula and securing them to vertebrae, inserting another fixation element such as a plate or rod through the single cannula, and securing the plate or rod to the pedicle screws. Foley Dec. ¶ 20. Clearly what was contemplated in the specification of the '044 Patent was a surgical procedure to install vertebral fixation elements, including two pedicle screws and another fixation element such as a plate or rod, through a single working channel cannula. Foley Dec. ¶ 20. The above discussion demonstrates that the Applicants were in possession of the subject matter alleged by the examiner to be unsupported.

To summarize:

- the specification of the '044 Patent repeatedly discloses using a ***single*** working channel cannula to perform the ***entire surgical procedure***;
- the specification discloses ***insertion of multiple vertebral fixation elements through the single cannula***, and one skilled in the art would readily understand that vertebral fixation elements include at least ***bone screws, plates and rods***;
- the specification discloses insertion of a pedicle screw through the single cannula, and one skilled in the art would readily understand that ***a pedicle screw is always***

***used in combination with a second anchoring-type fixation element (e.g., a second pedicle screw or a hook) secured to a second vertebra and another fixation element such as a plate or rod secured to the first and second fixation elements***; and

- the specification discloses that the single cannula is ***moved to different angles*** from a single incision site to perform the surgery, and this repositioning technique allows the surgeon to access ***various sites on different vertebrae with a single cannula*** during a surgical procedure.

- the specification literally supports newly added claim 9 as it literally discloses insertion of multiple fixation elements through a single cannula to fix a first vertebra with respect to a second vertebra as well as the inclusion of screws among the fixation elements

It is readily apparent, therefore, that the disclosure of the '044 Patent reasonably conveys to one skilled in the art that the Applicants had possession on March 22, 1996 of all the elements alleged by the Examiner on page 2 of the Office Action to be unsupported. Furthermore, even to the extent that the Examiner maintains that claims 1-8 are not supported, new claim 9 clearly finds literal support and sets forth the patentable invention.

With respect to the elements not mentioned by the Examiner in the Office Action, Applicants refer the Examiner to the claim chart attached as Appendix B to the Request for Interference. Appendix B demonstrates that claims 1-6 and 8 are entitled to the filing date of the '044 Patent (March 22, 1996) and that claim 7 is entitled to the filing date of U.S. Patent No. 5,902,231 (October 24, 1996). Accordingly, Applicants respectfully request that the Examiner reconsider his position that claims 1-8 are entitled only to the filing date of December 15, 2003, and conclude that claims 1-6 and 8 are entitled to the filing date of March 22, 1996 of the '044 Patent and that claim 7 is entitled to the filing date of October 24, 1996 of U.S. Patent No. 5,902,231.

On page 3 of the Office Action, claims 1-8 were rejected under 35 U.S.C. § 102(b) in view of PCT Publication No. WO 02/09801 to Davison ("Davison"). In view of the above remarks, Applicants respectfully submit that claims 1-6 and 8 are entitled to an effective filing date of March 22, 1996 and claim 7 is entitled to an effective fling date of October 24, 1996. Accordingly, Davison is not prior art and withdrawal of the rejection under § 102(b) is respectfully requested.

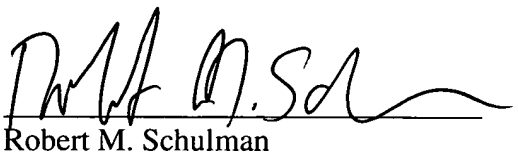
Having addressed all of the outstanding rejections of record, Applicants submit that the application is in condition for allowance and notice to that effect is respectfully solicited. If there are any questions regarding this Amendment or the Application in general, the Examiner is encouraged to contact the undersigned in order to expedite prosecution. Applicants' representative would welcome the opportunity to discuss the Application with the Examiner in an Examiner Interview.

Applicants are filing herewith a Petition for a 3-month extension of time and a check that includes the amount of $1020.00 to cover the required fee. It is believed that no additional fees are due for filing this Amendment. However, the Director is hereby authorized to treat any current or future reply requiring a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. Applicants also authorize the Director to charge any additional required fees or credit any overpayment of fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: July 3, 2006

By: 

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